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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,293	02/25/2002	Mark W. Leiby	68703/152	7984
26646	7590	03/19/2004		
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			EXAMINER MICHENER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER
			1762	
DATE MAILED: 03/19/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

38

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/084,293	LEIBY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jennifer K Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 10 and 18-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9 and 11-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/23/02&amp;8/11/03</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I and the stent substrate is acknowledged.

### ***Information Disclosure Statement***

2. The information disclosure statement filed 5/23/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

As noted on the copy of this IDS, Examiner *has* considered the U.S. references, but was unable to find copies of the non-patent literature documents in the application file. Submission (or re-submission) of these documents would be greatly appreciated and consideration thereof will be noted in the next office action.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-4 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The word "isotropically" is unclear. The specification states that a cloud of turbulent coating is formed due to the ultrasonic nozzle and the evaporation of the solvent prior to impact, however it is unclear to Examiner how a turbulent cloud can create isotropic impact. Webster's and Hack's defines isotropic as exhibiting properties with the same values when measured along axes in all directions. If a turbulent, chaotic cloud encompasses a substrate, the properties would not appear to Examiner to have the same values in all directions. Also, it is not clear to what properties Applicant refers. Properties of impact could include droplet size, speed, direction, and force, among others.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 11-13, 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (6,153,252).

Hossainy et al. teach a process for coating a stent substrate with an organic compound in a containment system by spraying an organic (polymeric) compound in solvent

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(liquid) via an ultrasonic nozzle to form micron-sized droplets, which impact on the substrate. Hossainy teaches subsequent drying, which removes the solvent (Example 6). Hossainy's containment system is used to slow evaporation and functions as Applicant's chamber. The pressure used by Hossainy is inherently controlled. Since the containment system is used to slow evaporation, the liquid is inherently volatile because evaporation occurs. Since the same type of SonoTek ultrasonic nozzle, droplet size, volatile liquid (col. 6, line 66), "cloud" coating formation, and substrate is used by Hossainy as by Applicant, the microdroplets formed by Hossainy must inherently impact "isotropically" on the surface of Hossainy's stent in the same manner of impact as Applicant's method.

7. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Versteeg et al. (5,451,260).

Versteeg teaches using an ultrasonic nozzle liquid delivery system to form a thin film on a substrate. The substrate of Versteeg is placed in a vacuum chamber. A mixture of a volatile liquid with organic compound therein is prepared (col. 3, lines 24-27; col. 5, line 54). In the batch operation, a discreet amount of the coating mixture is metered into a storage line (col. 4, line 39). The chamber is evacuated by Versteeg (col. 3, lines 57-58). Versteeg supplies an inert gas to the chamber (col. 3, line 23). Versteeg controls the pressure in the chamber (col. 4, lines 2-3). The mixture of Versteeg is introduced into the chamber via an ultrasonic nozzle to form a cloud for coating the substrate.

While Versteeg does not teach that the cloud is formed of micro-droplets for isotropic impact, Examiner notes that Versteeg teaches a fine mist of very small droplets (col. 2, line 10). Since Versteeg teaches all method limitations of Applicant and uses the same Sono-Tek ultrasonic spray device, the droplet size and impact would inherently meet these limitations of Applicant.

Regarding the limitation for drying the thin film, Examiner notes that the pressure of Versteeg is controlled to preferably volatilize the liquid prior to impact. However, Applicant's instant specification teaches the use of pressure to control the rate of evaporation of the liquid with examples inclusive of applying a coating with droplets that are nearly dry at impact to achieve uniformity of thickness on the substrate (p. 6, line 10). Since Applicant's process conditions are stated to be adjusted to achieve a full range of values, up to the almost completely dry status of the droplets, the instant method approaches a completely dry vapor deposition state as taught by Versteeg. The difference between Applicant's almost completely dry embodiment is not patentably distinct from Versteeg's dry embodiment. Additionally, it is Examiner's position that there would inherently be some small amount of liquid present in the coating of Versteeg which would subsequently evaporate off and "dry" as required by Applicant's claim.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-4, 8, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. in view of Versteeg et al.

Hossainy et al. teach that which is disclosed above regarding coating a medical device in a chamber with an organic compound solution in a cloud formation with a Sono-Tek ultrasonic coater and then drying the coating. Hossainy et al. teaches that control of

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solvent evaporation is achieved by using a containment device, but fails to teach the mechanism and specifics of the use of such evaporation-control device.

Versteeg teaches that which is disclosed above regarding coating a substrate in a cloud of organic material formed in a pressure-controlled chamber and applied with a Sono-Tek ultrasonic coater using a metering, evacuating, and purging step as outlined above. Since Hossainy and Versteeg both coat substrates with organic materials using the same ultrasonic coaters in a chamber and Versteeg specifically teaches the use of metering, evacuating, purging, and pressure-controlling to control evaporation of the solvent as also desired by Hossainy, Versteeg would have reasonably suggested the use of metering, evacuating, and purging, in the method of Hossainy. It would have been obvious to one of ordinary skill in the art to use the metering, evacuating, etc. conditions of Versteeg in the method of Hossainy to provide reproducible, uniform coatings in the method of Hossainy.

Hossainy's stent includes drug layers which inhibit restenosis.

It would have been obvious to use Versteeg's inert gases to dry the coating of Hossainy.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy in view of Versteeg as applied to claims 1, 3-4, and 8 above, and further in view of Tedechi.



Hossainy in view of Versteeg teach that which is disclosed above including a method of coating stents with polymer coatings with drugs incorporated therein, but fails to specifically teach that the polymer coating may be a derivatized silane.

Tedechi teaches coating stents with derivatized silane polymer with drugs incorporated therein to provide a thromboresistant, biocompatible coating.

Since Hossainy in view of Versteeg teach coating stents with polymers and Tedechi teaches a suitable polymer for coating stents, Tedechi would have reasonably suggested the use of derivatized silane as the polymer in Hossainy in view of Tedechi. It would have been obvious to one of ordinary skill in the art to use the teachings of Tedechi in the method of Hossainy in view of Versteeg to provide a biocompatible, thromboresistant coating in the method of Hossainy in view of Versteeg.

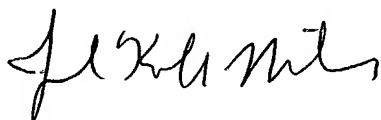
### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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March 11, 2004